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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,611	08/26/2008	Steven Siegel	P-7562-US	7210

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EXAMINER	
AL-AWADI, DANAH J	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,611	SIEGEL ET AL.	
	Examiner	Art Unit	
	DANAH AL-AWADI	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *21-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10 pages/02/05/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-45 are pending.

Applicant's election **without** traverse of the subject matter of group I in the reply filed on 16 June 2010 is acknowledged.

Claim 21-45 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim.

Information Disclosure Statement

Information Disclosure statement filed on 05 February 2008 is acknowledged and has been reviewed.

Claim Rejections- 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13, 15, 17-20 rejected under 35 U.S.C. 103(a) as being unpatentable over Siegel et al. US 2002/0179096.

Siegal et al. teaches a surgically implantable drug delivery system for long-term delivery of the antipsychotic drug – haloperidol (see Abstract); (page 2, paragraphs 0019-0021). The implantable delivery system contains a biodegradable polymer, preferably a lactide-glycolide copolymer (page 1, paragraph 0002); (page 3, paragraph 0023). Siegel et al. discloses an implant of polylactide-co-glycolide, one phase of which has slow release, the other having a faster release (paragraph 0024). The implant is specifically indicated for the treatment of psychotic disorders ((paragraph 0021) and (0032)). The implantable delivery system comprising the antipsychotic drug haloperidol provides superior treatment outcomes due to improved medication adherence. The implants are designed to last for months to years. Advantages of the implants include lower dosing,

steady state serum drug levels and increased bioavailability (page 2, paragraph 0022). The implants can be removed and thus offers a degree of reversibility (page 1, paragraph 0010).

It is noted that Siegel does not teach their implant to be a "rod-shaped" structure. However, the particular shape of the implant would be based on personal preference and/or the particular intended use of the implant. Moreover, an effective shape can be determined by one of ordinary skill in the art in order to provide an optimal outcome. The particular shape of the implant being claimed does not render a patentable distinction over the disclosure of Siegel who clearly recognizes and teaches an implantable drug delivery system comprising an antipsychotic drug (haloperidol) in combination with biocompatible polymers, such as polylactic acid and polyglycolic acid, whereby the implant is removable and is effective for the treatment of psychotic disorders and conditions.

Thus, the instant invention would be *prima facie* obvious to one of ordinary skill in the art, given the teachings of Siegel.

It would have been obvious to the skilled artisan at the time the invention was made to have administration of two formulations because it is routine in the art to administer drugs to the same patient in multiple different dosage forms in order to achieve a particular therapeutic affect.

With regards to the limitations "whereby administering said first and second formulation results in therapeutic circulating levels of said drug, for a period of about 14-120 days, thereby being a method of treating a nervous system disorder", until some material difference(s) in the properties of the composition are demonstrated, said

limitation is considered by the Examiner to be directed towards the drug formulation which is instantly claimed. Furthermore, the limitation having circulating therapeutic levels of the drug is future intended use as a result of the composition being implanted and is given little patentable weight. Absent evidence to the contrary, it is expected that the formulation would achieve the same circulating levels as claimed.

Siegel teaches subcutaneous delivery (paragraph (0013)). Furthermore, Siegel teaches implantable drug delivery devices (abstract). These devices are fully capable of being implanted subcutaneously.

Siegel teaches that the implant comprises a PLGA (polylactic acid to polyglycolic acid) ratio of 75:25 (paragraph (0024)). Therefore, as per pending claim 9, the implants vary in terms of drug concentration, polymer composition, or combination thereof.

Siegel teaches that the therapeutic drug is present in an amount of 30%-60% of the mass of the implant (paragraph (0023)).

With regards to administration of the formulations, it would have been obvious to one of ordinary skill in the art to administer the formulation within 1-24 hours, cyclically, or within 160-200 days in order to achieve an additive synergistic effect of the drugs while prolonging the effect of the drug.

Claim 13 and 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Siegel et al. US 2002/0179096 as applied to claims 1-13, 15, 17-20 above, and further in view of Sidman US Patent 4, 352, 337.

Siegel does not disclose a rod shaped implant having a diameter of about 1 to 2mm, a length between about 10 and about 40 nm, or a combination thereof, however, Sidman teaches a rod-shaped implantable drug delivery device (col. 10 line 62-64 Fig 2).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to formulate the implants as taught by Siegel into the shape of rods because it would have been obvious to one of skill in the art to form the implants in a shape that is desirable for ease of administration.

Sidman further teaches that the implant has a diameter between 2-4mm(col. 22 lines 45-40).

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Siegel et al. US 2002/0179096 as applied to claims 1-13, 15, 17-20 above, and further in view of Kino *et al*. U.S. Pat. No. 5,871,778.

Siegel as discussed above, teaches a surgically implantable drug delivery device for long-term delivery of the antipsychotic drug – haloperidol (abstract and paragraph 0019-0021). Siegel teaches the antipsychotic drug – haloperidol, used to treat psychotic disorders such as schizophrenia (paragraph 0032). Siegel discloses risperidone as a known antipsychotic drug (paragraphs (0009) and (0014)). While Siegel does not teach the antipsychotic drug – risperidone, for use in the invention, both of these drugs - haloperidol and risperidone are well-known effective psychotic medications useful for the treatment of psychotic disorders and would have equivalent efficacy, as evidenced by Kino.

Kino teaches a sustained release microsphere preparation produced by combining an antipsychotic drug such as haloperidol or risperidone with polymers such as polylactic acid, polyglycolic acid or the like (see column 2, line 45 - col. 3, line 16); Claims 5 and 8. The preparation of Kino aims to improve the maintenance therapy and increase patient

compliance with hydrophobic antipsychotic drugs (col. 2, lines 15-29); (col. 2, lines 5-20). Additional antipsychotic drugs are disclosed at column 2, lines 45-55.

It would have been obvious to one of ordinary skill in the art in order to employ any antipsychotic drug, particularly risperidone, such as that taught by Kino, within the delivery systems of Siegel. One would do so with a reasonable expectation of success because Kino teaches preparations with the incorporation of antipsychotic drugs such as risperidone, haloperidol and the like which are known for their therapeutic efficacy of mental conditions (i.e., schizophrenia, bipolar disorder). The preparations enable improved patient compliance and effectively provide for the treatment and therapy of mental disorders and psychotic conditions. The expected result would be an improved drug delivery system comprised of antipsychotic agents for effectively combating psychotic disorders.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danah Al-awadi whose telephone number is (571) 270-7668. The examiner can normally be reached on 9:00 am - 6:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For

more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DA/
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615